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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,186	11/04/2003	Joseph L. Duffy	21167	6239

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EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*JH*

## Office Action Summary

Application No.

10/701,186

Applicant(s)

DUFFY ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

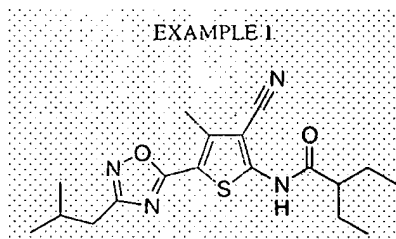
- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/6/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

**Claims 1-18 are pending in the application.**

### *Election/Restrictions*

Applicants' election with traverse of Group I (claims 1-16), and the species of Example 1 (reproduced below) found at the bottom of page 28, in the reply filed on December 22, 2004 is acknowledged.



The traversal is on the ground(s) that: (1) the method of treatment of claims 17 and 18 have been mischaracterized as a “process of use”; (2) the method of treatment claims addressing the use of the compounds of formula I are properly combinable with the compound claims of Group I; and (3) neither the process for using the product as claimed can be practiced with another materially different product nor the product as claimed can be used in a materially different process of using the product is on point.

Applicants' arguments have been considered but have not been found persuasive. As stated in 35 U.S.C. 101, the term "process" includes a method. See except from M.P.E.P. 2106 (reproduced below).

#### **IV. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 101**

As cast, 35 U.S.C. 101 defines four categories of inventions that Congress deemed to be the appropriate subject matter of a patent, namely, processes, machines, manufactures and compositions of matter. The latter three categories define "things" while the first

category defines "actions" (i.e., inventions that consist of a series of steps or acts to be performed). See 35 U.S.C. 100(b) ("The term process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material").

As stated in the Restriction Requirement of December 10, 2004, the process for using the product as claimed can be practiced with another materially different product. For instance, there are drugs (other than the instant claimed compounds) on the market that treat type 2 diabetes mellitus. Therefore, a restriction between the products and the method of use is proper. Further, in accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is

deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The requirement is still deemed proper and is therefore made FINAL.

Claims 17 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in the reply filed on December 10, 2004.

***Information Disclosure Statement***

The Information Disclosure Statement filed on February 6, 2004 has been considered by the Examiner.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 16 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 10/706,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant products are generically described in the copending application. See in claim 14 of the copending application wherein R<sup>1</sup> is alkyl; R<sup>2</sup> is alkyl substituted with R<sup>6</sup> (e.g., trifluoromethyl); and R<sup>3</sup> is alkyl.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed

compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating type 2 diabetes mellitus).

One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating type 2 diabetes mellitus. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-9 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Al-Omron et al. {Journal of Heterocyclic Chemistry (September-October 2002), 39(5), pages 877-883}.

Al-Omron et al. disclose compound 15 (Scheme 2 on page 878; and page 881, top of second column) that is embraced by the instant claimed invention when  $R^1$  is alkyl (e.g., methyl),  $R^2$  is heteroaryl (e.g., benzotriazole) and  $R^3$  is alkyl (e.g., methyl). Therefore, the instant claims are anticipated by Al-Omron et al.

Claims 1, 5-9 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Cao et al. {US 2004/0122016}.

Cao et al. disclose, for example, Compound I-A-2 on page 31 that is embraced by the instant claimed invention when  $R^1$  is hydrogen,  $R^2$  is heteroaryl (e.g., pyridyl) and  $R^3$  is alkyl substituted with  $R^6$  (e.g., phenylmethyl). Therefore, the instant claims are anticipated by Cao et al.



*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cao et al. {US 2004/0122016}, Hagen et al. {U.S. Pat. 5,422,335} and Kawai et al. {U.S. Pat. 6,048,880}, each taken alone or in combination with each other when similar utilities are asserted.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim thiophene compounds. Cao et al. {paragraphs [0031]-[0048] on pages 5-6; paragraph [0064] on page 7; paragraph [0131] on page 24; paragraphs [0206]-[0222] on pages 115-118; and especially Compound I-A-2 on page 31}}, Hagan et al. {column 1, lines 5-51; column 2, lines 1-31; column 51, lines 31-41; column 52, lines 39-61; and especially the compounds Nos. 14.01, 14.04, 14.13, etc. in Table 14, columns 55-56} and Kawai et al. {columns 3-5; column 9, line 19; column 10, lines 60-61; column 15, lines 51-64; and column 16}

each teach thiophene compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., inhibitors of protein kinases).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, asthma. Additionally, since Cao et al. and Kawai et al. each teach thiophene compounds, which are structurally similar to each other, and are useful in treating, for example, asthma, the combination of Cao et al. and Kawai et

al. would also teach the instant claimed invention. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

***Allowable Subject Matter***

Claims 11 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

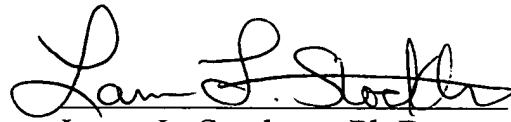
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/701,186  
Art Unit: 1626

Page 11

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

March 3, 2005